

## **REMARKS**

Claims 3-12 and 14-17 are pending in this application. None of the claims have been amended. Accordingly, claims 3-12 and 14-17 remain pending and under examination. In view of the remarks provided herein, Applicants respectfully request favorable reconsideration and allowance of the claims.

### **Claim Rejections - 35 USC §103**

The rejection of claims 3-12 and 14-17 under 35 U.S.C. §103(a), as being obvious over Hiserodt *et al.* (US patent No. 6,277,368) and in view of Ferrante *et al.* (Cancer Chemother. Pharmacol., 43(Suppl.): S61-S68, 1999) has been maintained from the previous office action. More specifically, the Examiner has asserted that it would be obvious to one of ordinary skill in the art to combine the components taught by Hiserodt *et al.* and Ferrante *et al.* in the same composition for treating cancer. Applicants respectfully traverse the rejection.

The Examiner has asserted that the claimed product can be viewed as combination of ingredients known in the art to be useful for the same purpose, namely cancer therapy, and that such a composition is obvious in view of *In re Kerkhoven* (*In re Kerkhoven*, 626 F.2S 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). The court in *In re Kerkhoven* held that it is obvious to combine two compositions to form a third when each of the two compositions is taught by the prior art to be useful for the same purpose.

Applicants respectfully submit that “cancer therapy” is an overly broad concept for evaluating identity of purpose, and hence is an inappropriate standard for applying *In re Kerkhoven*. The claims at issue in *In re Kerkhoven* related to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents. Spray-dried detergents are a specific, well-identified application using similar technology. Cancer therapy, on the other hand, is an enormously broad category including a wide variety of significantly different treatment modalities. Cancer therapy includes, for example, the use of anti-angiogenic agents, use of antisense oligonucleotides, gene therapy, use of immunotoxins, use of photosensitizing agents, hormone therapy, use of various cytokines, vaccination, and a wide variety of chemical approaches using fundamentally different mechanisms of action. All of these different approaches fall under the broad heading of “cancer therapy,” but actually have very

different specific purposes, such as preventing blood flow to cancer cells, stimulating an immune response to cancer cells, or inducing apoptosis in rapidly proliferating cells. Applicants encourage the Examiner to consider the absurdity of finding obvious all combinations of ingredients useful for the purpose of “improving health,” and how this illustrates the importance of selecting a category with an appropriate breadth when determining whether or not two compositions are being used for the same purpose.

The Federal Circuit has addressed this issue in *In re Geiger* (2 USPQ.2d 1276; 815 F.2d 686 (Fed. Cir. 1987)) in which the Federal Circuit held that the PTO failed to establish a *prima facie* case of obviousness when chemicals from 3 references, which provided differing chemical compositions for preventing scale formation, were combined to provide a new composition for inhibiting scale formation. The USPTO initially held that the combination was obvious, citing *In re Kerkhoven*. However, the court noted that the composition in one reference was used for treatment of cooling water systems, while in the other reference the composition was used for the treatment of a boiler water system, and that these two conditions were significantly different. While both references were being used for the overall purpose of preventing scale formation, the different purposes of preventing scale formation in a cooling water system and a boiler water system were sufficiently different that they did not constitute “the same purpose” as required by *In re Kerkhoven*. Accordingly, it is important to define the purpose of compositions narrowly when applying *In re Kerkhoven*, and not conclude that it is obvious to combine chemicals that provide a similar result when they do so in a different fashion or under different conditions.

Returning to Applicant’s claims, Applicant’s note that Hiserodt *et al.* describes anti-cancer vaccines made from cytokine -secreting cell lines combined with a tumor-associated antigen. As further described in the abstract, these compositions have the purpose generating an immune response against specific tumor antigens. Ferrante *et al.*, on the other hand, as noted by the Examiner, teaches the use of chemotherapeutic agents such as taxane, paclitaxel, doxorubicin, and cisplatin as anti-cancer agents. While these chemotherapeutic agents differ somewhat from one another in their mechanisms of action, they generally operate by crosslinking or intercalating DNA, thereby inducing cell apoptosis, and therefore have the purpose of inducing apoptosis in rapidly proliferating cells. The compounds taught by Hiserodt *et al.* therefore do not have the same purpose as the compounds taught by Ferrante *et al.*, when

evaluated in view of *In re Geiger*, and as a result they should not be combined to render the present claims obvious under the principle that it is obvious to combine two compositions to form a third when each of the two compositions is taught by the prior art to be useful for the same purpose as held in *In re Kerkhoven*. Applicants respectfully request that the rejection of claims 3-12 and 14-17 under 35 U.S.C. §103(a), as being obvious over Hiserodt *et al.* in view of Ferrante *et al.* be withdrawn.

The rejection of claims 3-12 and 14-17 under 35 U.S.C. §103(a), as being obvious over Wang *et al.* (Cancer Immunol., 1986) and in view of Ferrante *et al.* (Cancer Chemother. Pharmacol., 43(Suppl.): S61-S68, 1999) has also been maintained from the previous office action. More specifically, the Examiner has asserted that it would be obvious to one of ordinary skill in the art to combine the components taught by Wang *et al.* and Ferrante *et al.* in the same composition for treating cancer, again based on the holding of *In re Kerkhoven*. Applicants respectfully traverse the rejection.

As Applicants have noted above, the term “cancer therapy” is too broad a term for characterizing purpose for an obvious determination according to *In re Kerkhoven*, and that it is necessary to look at the purposes of the compounds taught in the references using more a more useful and narrowly defined purpose in view of *In re Geiger*.

Ferrante *et al.* teaches the use of chemotherapeutic agents such as taxane, paclitaxel, doxorubicin, and cisplatin that have the purpose of inducing apoptosis in rapidly proliferating cells. Wang *et al.*, on the other hand, teaches use of the compound CL 259,763 as an immunomodulating agent for the purpose of increasing the immune response to tumor cells. The purpose of the composition described in Ferrante *et al.* is therefore different from the purpose of the composition described in Wang *et al.*, and it is thus improper to characterize the present claims as being obvious in view of these two references by applying the holding of *In re Kerkhoven*. Accordingly, Applicants respectfully request that the rejection of claims 3-12 and 14-17 under 35 U.S.C. §103(a) as being obvious over Wang *et al.* in view of Ferrante *et al.* be withdrawn.

Finally, should the Examiner maintain that the purpose of the present invention and the prior art is best evaluated as “cancer therapy”, Applicant’s respectfully submit that it is well

known in the art that a method of providing cancer therapy is both a long-felt need, and one for which there have been numerous examples of failure by others, both of which are sufficient to rebut a *prima facie* case of obviousness. Applicants' have provided a novel method of treating cancer, as claimed, which is not anticipated by the prior art in a heavily studied and important field, and the claims should not be rejected on the basis that it would be obvious to combine any techniques known in this diverse field merely because they share the overall purpose of being useful for cancer therapy.

The present response raises no new issues, nor would it entail the need for further search on the part of the Examiner. In view of the remarks, Applicant's submit that claims 3-12 and 14-17 are in condition for allowance, and respectfully requests their allowance. In the event that there are any questions concerning this response, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

Date: December 4, 2009

By: /Raymond N. Russell/

Raymond N. Russell, Ph.D.,

Reg. No. 52,185

(216) 622-8373